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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,656	06/20/2003	Bill E. Cham	13131-0310 (44378-282108)	8075

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/20/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,656	CHAM ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,31 and 33-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,31 and 33-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/311,679.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response filed September 19, 2006 is acknowledged and entered. Claims 1, 2, 28-31 and 33-54 are pending and under examination.

The rejection of claims 1, 29-31, 33-47 and 49-51 under 35 U.S.C. 102(b) as being anticipated by Naficy (US Patent 5,419,759) is withdrawn. Upon further consideration of the teachings of Naficy as a whole, the claimed invention is not taught or fairly suggested by Naficy's apheresis method.

Priority

The Office notes that the instant claims have priority to provisional application, USSN 60/390,066, filed June 20, 2002. The instant claims are drawn to subject matter that was not present in the parent application, USSN 10/311,679. The subject matter that is entitled only to the benefit of the filing date of the provisional application is, "at least one exposed epitope not usually presented to an immune system of the animal or the human by the non-delipidated viral particle", among other newly presented subject matter. Therefore, the art rejections are based on the date of priority for this application, June 20, 2002.

Claim Rejections - 35 USC § 112

Claims 48 and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. This is a new matter rejection. The claims recite a concentration ("0.3% to 2.5%") that does not appear to have been contemplated in the specification or the claims as originally filed.

Claim Rejections - 35 USC § 102

Claims 1, 2, 28-31 and 33-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Barrett et al. (US 6,136,321, "Barrett", filed February 10, 1998). The claims are drawn to a modified immunodeficiency virus particle comprising at least a partially delipidated immunodeficiency virus particle that initiates a positive immune response in an animal or human patient and incites protection against an infectious organism. (The infectious organism is understood to be the same species (HIV, SIV, FIV, etc.) as the delipidated viral particle.) The specification indicates that the viral particle is modified by exposing a non-delipidated viral particle to a delipidation process wherein the lipid content of a virus is reduced. The particle is not infectious, yet remains immunogenic and exposes epitopes that are not usually presented to the immune system by untreated virus. The virus particle proteins are structurally changed by the delipidation process on, in or near the surface of the virus (page 20, lines 10-23). Particular epitopes include gag, p6, gp66, gp41, p27 or env. The modified viral particle retains over 90% of major protein constituents.

Barrett discloses a method of inactivating lipid-enveloped viruses. The method involves a non-ionic detergent from the group of polysorbates for a period of time to completely inactivate the virus particle without affecting its structural integrity and particularly the biological activity of its surface and envelope proteins (col. 3, lines 1-15). Viruses that are

inactivated by the disclosed method include all enveloped viruses, including retroviruses, such as SIV, HIV-1 and HIV-2 (col. 2, lines 50-59, and col. 3, lines 38-45). Barrett discloses that the biological activity of HIV's CD4 binding function is not affected by the inactivation (col. 3, lines 50-52).

In Examples 1-3, Barrett describes the inactivation of HIV-1, HIV-2, influenza and pseudorabies virus (PRV). The viruses are purified via sucrose gradient centrifugation and dialysis. The purified preparation is admixed with octyl glucoside or polysorbate 80 for one hour. The presence of HIV proteins was measured after the inactivation, and gp120 and gp140 were detected.

Barrett uses polysorbate 80 in particular because it is considered to be compatible for humans and is frequently used in foods and cosmetics (col. 5, lines 12-18). The concentration of the polysorbate is in a range of between 1% and 25%. Barrett also discloses that the inactivated virus may be formulated with pharmaceutically acceptable and physiologically acceptable carriers, such as ionized water, PBS, salts, amino acids and non-ionic detergents for stabilizing purposes (col. 6, lines 14-27). The composition may also contain an adjuvant (immunostimulant) such as mineral oils, immunomodulators and immunopotentiators (col. 6, lines 28-37).

Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

The claimed method steps of making the compositions do not lend patentability to the claims. The method steps are not expected to result in a structurally different and functionally different product than Barrett because the method steps of Barrett use the same organic solvent as Applicant: polysorbates (surfactants). Even though claim 44 has been amended such that surfactants are not included in the Markush group of organic solvents, the effect of the surfactants is expected to be the same as the other solvents that are still recited in claim 44. The surfactants and the other solvents in claim 44 are functional equivalents, since they were/are included in a Markush group. Even in the claims that recite alcohols as the organic solvent, one expects the resulting viral particle to be the same as Barrett's viral particle that has reduced lipid content yet remains biologically active. Therefore, the invention as a whole is anticipated by the prior art.

Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

Applicant argues that the instant claims are directed to modified viral particles comprising at least partially delipidated viral particles. Applicant asserts that Barrett does not disclose partially delipidated viral particles and is silent as to the lipid content in its viral particles. Applicant also argues that Barrett uses non-ionic surfactants, particularly polysorbate, for inactivating lipid enveloped viruses. Applicant asserts that one would not expect that viral particles treated with a detergent would be the same as viral particles partially delipidated with an alcohol.

In response to Applicant's arguments, Barrett teaches that the integrity of the inactivated particles is not affected and that the particles retain biological activity of its surface and envelope

proteins (col. 3, lines 1-15). Although Barrett does not discuss the lipid content of the resulting inactivated particles, the method by which the particles are made is the same as the method used by Applicant. Whether one uses a surfactant or an alcohol, the result is expected to be the same. The reason for this expectation is that Applicant's own invention lists surfactants and alcohols (among other solvents) as acceptable for use in the invention. That means that Applicant deemed surfactants suitable for delipidating particles. Now Applicant asserts that the structure of a particle treated with a surfactant is different from a particle treated with an alcohol. The Office relies on the teachings of the specification and claims as filed, which indicated that surfactants and alcohols were functional equivalents, both being suitable for delipidating the claimed virus particles. Therefore, Barrett's virus particles (treated with a surfactant) are expected to have the same properties as Applicant's virus particles (treated with a functional equivalent).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12/15/06

Stacy B Chen

STACY B. CHEN
PRIMARY EXAMINER